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REMARKS

Favorable reconsideration of this application is requested in view of the foregoing amendment and the following remarks. New claims 49 and 50 have been added and claims 40 and 48 have been cancelled without prejudice or disclaimer. Therefore, claims 1-39, 41-46 and 49-50 are now currently pending.

Claim 1 is currently amended to indicate that the rehydration step occurs by immersion in either water or a salt solution where the salt solution has a less than 1% concentration of salt. Support for the amendment to claim 1 can be found in the fourth and fifth paragraphs of page 3 in the International Application. No new matter has been added with the amendment to claim 1.

Claims 1-46 have been rejected as being unpatentable over "Studies on the Hydration of Natural Anhydrite" by Murakami et al. in view of Soviet Patent Document No. 345,098 and further in view of U.S. Patent No. 5,248,487 to Bold et al.

Claim 1 of the present application, as amended, claims a method of producing surgical grade calcium sulphate. The method includes first forming an initial calcium sulphate di-hydrate from synthetic constituents. This initial calcium sulphate di-hydrate is then used to form calcium sulphate anhydrite. The calcium sulphate anhydrite is subsequently rehydrating by immersing in any one of water and a salt solution where the concentration of salt in solution is less than 1% which promotes subsequent calcium sulphate di-hydrate to crystallise out.

The present invention concerns surgical grade calcium sulfate, and particularly such material for use as a bone void filler. It is imperative that such a material have a very high purity, hence, the material is made from synthetic constituents. As noted in the specification on page 1, second paragraph, conventional techniques produce materials with high surface area which has a high water demand and therefore produce a low strength material when set. Such a material has a short dissolution rate when implanted. In the present invention, the calcium sulfate di-hydrate formed from synthetic constituents is dehydrated to form calcium sulfate anhydrite. The formed anhydrite is soluble in contrast to insoluble anhydrite as derived from natural sources such as natural anhydrite.

In present claim 1, the anhydrite is rehydrated with water to allow subsequent calcium

sulfate di-hydrate to crystallize out. The subsequent di-hydrate which crystallizes out has a relatively low specific surface area and, hence, water requirement. In contrast, the Murakami reference relates to the difficulties of hydrating natural anhydrite. The anhydrite of Murakami will therefore be of the insoluble “dead burnt” type. This anhydrite will not be synthetically formed and thus surgical grade which, in turn, would not be suitable for use in the method of present claim 1.

Attached as Exhibit A is a paper entitled “Studies on the Hydration of Natural Anhydrite” which clearly shows that the anhydrite of Murakami relates to natural anhydrite rather than synthetic anhydrous calcium sulfate. As discussed in the paper, the word “anhydrite” is not a generic term to describe anhydrous calcium sulfate, rather it is specifically the mineral anhydrite. “Anhydrite” defines a natural anhydrite (i.e., not synthetic) which is found in nature as a constituent of evaporite deposits typically associated with gypsum, alkali halides and carbonates. The paper adds that the sulfate mineral is also observed in submarine hydrothermal systems and in some igneous rocks. As stated in the Merck Index, Eighth Edition (Exhibit B) natural anhydrite is an orthorhombic in crystalline form and has a density of 2.96 g/cc. As discussed in the article, anhydrite cannot be easily hydrated, and for this reason is commonly referred to as insoluble anhydrite. Soluble anhydrite (γ -CaSO₄), on the other hand, is formed by completely dehydrating calcium sulfate dehydrate (either natural gypsum or synthetic) at relatively low temperatures (i.e., below about 360°C). This material has a tetragonal crystalline shape and a density of 2.61 g/cc. It readily absorbs water and hydrates, and, thus, is labeled soluble anhydrite.

It is quit clear from the above that natural anhydrite includes impurities that are highly undesirable in materials to be located within the human body. Attached as Exhibit C is a test report on synthetic material (FORTOSS) prepared from synthetic calcium sulfate. The test results show that only crystalline phases detected by x-ray diffraction are bassanite and anhydrite, both calcium sulfate materials. In contrast, Exhibit D shows test results from x-ray diffraction of naturally occurring calcium sulfate (CAPSET). As is apparent, this compound contained 1.3% dolomite and 0.3% quartz. Quartz is a very undesirable impurity since it is not bio-absorbed and is potentially toxic. Crystalline silica in respirable form is classified as a Group I carcinogen.

Attached as Exhibit E is a Press Release noting the dangers of respirable crystalline silica. In addition, a Material Safety Data Sheet for calcium sulfate is included as Exhibit F. The MSDS shows the presence of crystalline silica in the calcium sulfate and the silica's classification as a Group I carcinogenic. Therefore, by using a natural anhydrite one would not obtain surgical grade calcium sulfate as recited in claim 1. As such, it is respectfully submitted that synthetically formed anhydrite is more suitable for forming a surgical grade calcium sulfate than an anhydrite obtained from natural sources.

Further, the hydration of the anhydrite in Murakami is achieved through a salt solution such as a 15% solution of ammonium nitrate with continuous stirring. Present claim 1 has been amended to provide for immersion to take place in water or a dilute salt solution having less than about 1% salt in solution. This concentration of salt in solution is much lower than that recited in Murakami. In fact, water alone may be used for rehydration. Further, the present claim 1 does not require stirring, as is shown by the use of the expression "immersing" in the amended claim 1.

There are significant differences in the process described in Murakami and what is recited in claim 1. As shown by the referenced article and test results, Murakami does not concern synthetic constituents. In addition, Murakami requires the use of a salt solution having a high concentration of salt. Therefore, Murakami is quite different from the method of claim 1 and one of ordinary skill in the art would not look to Murakami to produce the surgical grade calcium sulfate as described in claim 1.

The Soviet document to Drozin does not cure the deficiencies of the Murakami reference. Specifically, Drozin does not teach one of ordinary skill in the art the method of recited claim 1. Drozin relates to preparing insoluble anhydrite. Drozin employs a very high concentration of salt (>70% Calcium Chloride) along with heating and stirring. The product of the Drozin reference would result in impurities from the use of the high concentration of salt. In addition, the Drozin process teaches stirring the solution. In contrast, present claim 1, as amended, calls for rehydration to take place through "immersing." Immersing in contrast to stirring produces larger crystal sizes which have a lower surface area and thus a low water requirement. Accordingly, Drozin does not remotely relate to surgical grade materials. Instead Drozin relates to producing

insoluble anhydrite from natural materials which would thus be wholly unsuited to use in surgical grade applications as discussed above.

As shown above, Murakami does not disclose, teach or suggest the method recited in present claim 1. Specifically, claim 1 calls for using a calcium anhydrite that was synthetically obtained from dehydrating calcium sulfate di-hydrate. Drozin does not disclose calcium sulfate di-hydrate being formed from synthetic constituents. Therefore, one of ordinary skill in the art would not look to Murakami in view of Drozin for a method of producing surgical grade calcium sulfate. Accordingly, claim 1 is patentable over the cited references and withdrawal of the rejection is respectfully requested.

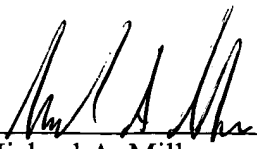
Claims 2-39 and 41-46 depend from claim 1. These dependent claims are patentably distinguished from the cited references for the same reasons as the claims from which they depend, as well as additional reasons. Specifically, U.S. Patent No. 5,248,487 to Bold et al. relates to a method of forming hemihydrate from di-hydrate and is not relevant to present dependent claims. Therefore, the Bold reference does not teach the features of the independent claims in view of the claim from which they depend. Since independent claim 1 is non-obvious under 35 U.S.C. § 103, then all claims depending from claim 1 are also non-obvious. As such, withdrawal of the rejection of these claims is respectfully requested.

Claims 49 and 50 have been added and are believed to be patentable over the cited art.

In view of the foregoing amendment and remarks, claims 1-39, 40-46 and 49-50 are now in condition for allowance. A favorable response to this Amendment in the form of a Notice of Allowance is hereby solicited.

Dated: 1/14/04

Respectfully submitted,



Michael A. Miller
Reg. No. 50,732

Anhydrite [CaSO₄]

Structure Orthorhombic

Space Group : *Amma* (No. 63)

$a=6.993 \text{ \AA}$, $b=6.995 \text{ \AA}$, $c=6.245 \text{ \AA}$

$\alpha=\beta=\gamma=90.00$

$Z=4$

Atomic Positional Parameters

Ca 4c 0.7500 0.0000 0.3476

S 4c 0.2500 0.0000 0.1556

O1 8g 0.2500 0.1699 0.0162

O2 8f 0.0819 0.0000 0.2975

Reference

FC Hawthorne and RB Ferguson (1975) *Canadian Mineralogist*, 13, 289-292

Mineral Chemistry

Anhydrite is found as a constituent of evaporite deposits, typically associated with gypsum, alkali halides and carbonates. This sulphate mineral is also observed in submarine hydrothermal systems, and in some igneous rocks. The structure of anhydrite comprises sulphate (SO₄) tetrahedra and calcium coordinated by eight oxygens. The name anhydrite derives from the composition of this mineral - there is no water of crystallisation, which distinguishes this phase from gypsum (CaSO₄·2H₂O).

Anhydrite cannot be hydrated easily. To form gypsum from anhydrite at low temperatures, dissolution and reprecipitation may be necessary. Direct heating of gypsum to about 360°C is required to form anhydrite; at lower temperatures, gypsum dehydrates to γ -CaSO₄. Anhydrite has retrograde solubility in water with temperature, but increases in solubility with pressure. Experimental formation of anhydrite under aqueous conditions which simulate evaporitic fluids has been explored by a number of researchers. Increased salinity decreases the temperature at which gypsum can transform to anhydrite, thus appearing to favour anhydrite formation, although the exact mechanism(s) of anhydrite formation in evaporites may still require further investigation.

The CHIME figure shows calcium ions as large spheres with the bonds from oxygens to calciums shown as thin red lines. This should make the sulphate tetrahedra easier to identify.

University of Colorado

Mineral Structure Data

Gypsum and Anhydrite

The crystal structure of gypsum.

Table 9.5.1. Gypsum and Anhydrite Unit Cells.

	Gypsum	Anhydrite
Formula	$\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$	CaSO_4
Form. Wt.	172.173	136.142
Density	2.313	2.953
Mol Volume	74.440	46.103
Z	4	4
Cryst. Sys.	Monoclinic	Orthorhombic
Cryst. Class	2/m	mmm
Space Group	I2/a	Amma
Cell Parameters		
a	5.670	7.006
b	15.201	6.998
c	6.533	6.245
beta	118.60	90.
Vol.	494.37	306.18
Thermal expansion		
alpha		
a ₀		
a ₁		
a ₂		
Elastic Properties		
K _s (GPa)		
G (GPa)		
Ref.	Cole & Lancucki (1974)	Kirfel & Will (1980)

d_{25}^{25} 2.10. Bulk density: 15 to 16 lb/cu ft. Absorbs 1 to 2½ times its weight of liquids and still remains a free-flowing powder. Total absorption power for water about 600%, for mineral oil about 500%. Available surface area: 95 to 175 m²/g. Ultimate particle size: 0.02 to 0.07 μ . pH of aq slurry 8.0 to 10.0. Practically insol in water. Forms a siliceous gel with mineral acids.

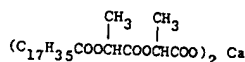
USE: Constituent (produced *in situ*) of lime glass, portland cement; reinforcing filler in elastomers and plastics; absorbent for liquids, gases, vapors; as anti-caking agent, suspension agent, pigment and pigment extender; binder for refractory material; in chromatography; in road construction. *Human Toxicity*: Practically nontoxic. Inhalation of the dust may cause irritation of respiratory tract.

Calcium Stearate. *Stearic acid calcium salt.* $\text{Ca}(\text{C}_{17}\text{H}_{35}\text{O}_2)_2$; mol wt 607.00. $\text{C}_{36}\text{H}_{70}\text{CaO}_4$; C 71.23%, H 11.62%, Ca 6.60%, O 10.54%. Prep'n: Harrison, *Biochem. J.* 18, 1222 (1924); Kebrich, Petrol, U.S. pat. 2,650,932 (1953 to National Lead Co.).

Granular, fatty powder. Bulk density about 20 lb/cu ft, mp 147-149° (determined by gradient bar). Practically insol in water, ether, chloroform, acetone, cold alcohol; slightly sol in hot alcohol, in hot vegetable and mineral oils; quite sol in hot pyridine.

USE: For waterproofing fabrics, cement, stucco, explosives; as a releasing agent for plastic molding powders; as a stabilizer for polyvinyl chloride resins; lubricant; in pencils and wax crayons. Food grade calcium stearate, derived from edible tallow, is used as a conditioning agent in certain food and pharmaceutical products.

Calcium Stearyl-2 Lactylate. *Stearic acid, ester with lactate of lactic acid, calcium salt;* Verv-Ca. $\text{C}_{48}\text{H}_{96}\text{CaO}_{12}$; mol wt 895.30. C 64.40%, H 9.68%, Ca 4.48%, O 21.45%. Commercial development: C. J. Patterson Co., Kansas City, Mo.



Free-flowing, nonhygroscopic, powder. Sparingly sol in water. pH of a 2% aq suspension 4.7.

USE: To improve the mixing characteristics of flour: Thompson, Buddemeyer, *Cereal Chem.* 31, 296 (1954); to improve whipping and baking properties of dried egg whites: Gorman, Keith, U.S. pat. 2,919,992 (1960 to Seymour Foods, Inc.). *Human Toxicity*: Practically nontoxic.

Calcium Succinate. *Succinic acid calcium salt;* Artume. $\text{CaC}_4\text{H}_4\text{O}_4$; mol wt 156.15. C 30.77%, H 2.58%, Ca 25.67%, O 40.98%. Prep'n: Beilstein vol 2, 607, 2nd suppl., 548, 3rd suppl., 1657.

Trihydrate, $\text{CaC}_4\text{H}_4\text{O}_4 \cdot 3\text{H}_2\text{O}$, needles or granules. Slightly sol in water; practically insol in alcohol; sol in dil acids.

MED USE: Combined with salicylates as analgesic.

Calcium Sulfate. CaSO_4 ; mol wt 136.14. Ca 29.44%, O 47.01%, S 23.55%. Review: Hammond in Kirk-Othmer *Encyclopedia of Chemical Technology*, vol. 4 (2nd ed, Interscience, 1964), pp 14-27.

Anhydrous, CaSO_4 . The natural form of anhydrous calcium sulfate is known as the mineral *anhydrite* (karstenite, *muricite*, *anhydrous sulfate of lime*, *anhydrous gypsum*). The crystals are orthorhombic, the color varies, e.g., white, with blue, gray or reddish tinge, or brick red. d 2.96. Hardness 3-3.5 (Mohs). Solubility in water at 18.75° 0.2 pts/100 pts. *Insoluble anhydrite* (dead-burned gypsum) which has the same crystal structure as the mineral is obtained upon complete dehydration of gypsum at above 650°. *Soluble anhydrite* is obtained in granular or powder form by complete dehydration of gypsum at below 300° in an electric oven. Estimated pore space is 38% by volume. Possesses high affinity for water and will absorb 6.6% of its weight of water, forming the stable hemihydrate $\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$.

Hemihydrate, $\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$, dried calcium sulfate; plaster of Paris; Anallin; dried gypsum. Fine, odorless, tasteless powder. When mixed with water, sets to a hard mass. Keep well closed.

Dihydrate, $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$, native calcium sulfate; precipitated calcium sulfate; gypsum; alabaster; selenite; terra alba; satinite; mineral white; satin spar; light spar. Lumps or powder. d 2.32. It loses only part of its water at 100-150°.

Soluble in water; very slowly sol in glycerol; practically insol in most organic solvents.

USE: *Anhydrous*: Insol anhydrite is used in cement formulations and as a paper filler. Soluble anhydrite, because of its strong tendency to absorb moisture, is useful as a drying agent for solids, organic liquids and gases; the desiccant used in laboratory and industry is known under the name *Drierite*. This material can be regenerated repeatedly and reused without noticeable decrease in its desiccating efficiency. The *hemihydrate* is used for wall plasters; wallboard; tiles and blocks for the building industry; moldings; statuary; in the paper industry. The *dihydrate* is used in the manuf of portland cement; in soil treatment to neutralize alkali carbonates and to prevent loss of volatile and dissolved nitrogenous compounds by volatilization and leaching; for the manuf of plaster of Paris, artificial marble; as a white pigment, filler or glaze in paints, enamels, pharmaceuticals, paper, insecticide dusts, yeast manuf, water treatment, polishing powders; in the manuf of sulfuric acid, CaC_2 , $(\text{NH}_4)_2\text{SO}_4$, porous polymers.

MED USE: For making plaster supports (casts).

Calcium Sulfide. CaS ; mol wt 72.14. Ca 55.56%, S 44.44%. Pure CaS prep'd in the laboratory by heating pure CaCO_3 in a stream of H_2S + H_2 at 1000°: Ehrlich in *Handbook of Preparative Inorganic Chemistry*, G. Brauer, Ed., (2nd ed, Academic Press, 1963), p 938.

Calcium sulfide, crude. Erroneously called: "sulfurated lime," "calcic liver of sulfur," "liver of lime," "hepar calcis." Made by igniting calcium sulfate with carbonaceous matter. Contains not less than 55% CaS ; the balance is calcium sulfate, sulfite and carbonate, and the "ash" from the carbonaceous material. Mellor, *A Comprehensive Treatise on Inorganic and Theoretical Chemistry*, vol. III (Longman's, 1928), p 740.

Calcium sulfide, luminous, *Canton's phosphorus*. Made by igniting a mixture of CaCO_3 and S with very small quantities of Bi or Mn salts, etc.: Mellor, *loc. cit.*; Verneuil, *Compt. Rend.* 103, 600 (1886).

White powder if pure; crude and luminous calcium sulfide may be yellowish to pale-gray. Odor of H_2S in moist air; unpleasant alkaline taste. Oxidizes in dry air and dec in moist air. mp > 2000°. d 2.59. Slightly sol in cold, more sol in hot water with partial decompn; freely sol in solns of ammonium salts; practically insol in alcohol; dec even by weak acids, evolving H_2S . Keep well closed.

USE: In phosphors; as food preservative; as lubricant additive. Pure CaS used in electron emitters. Luminous CaS used for making luminous paints or varnishes.

VER USE: Has been used in chronic suppurations, such as boils, fistulae, etc.

Calcium Sulfite. CaSO_3 ; mol wt 120.14. Ca 33.36%, O 39.95%, S 26.69%. Prep'n: *Gmelin's Handb. anorg. Chem.*, System no. 28 (Calcium), part B, 8th ed, pp 107, 660-674 (1958).

Dihydrate, $\text{CaSO}_3 \cdot 2\text{H}_2\text{O}$, crystals or powder. Slowly oxidizes in air to CaSO_4 . Slightly sol in water, alcohol; sol in SO_2 solns, acids with liberation of SO_2 .

USE: Preserving cider and other fruit juices; as disinfectant of brewing vats; antichlor in bleaching textiles; in sugar manuf; in paper pulp cooking; in cement.

Calcium Tartrate. $\text{CaC}_4\text{H}_4\text{O}_6$; mol wt 188.15. C 25.53%, H 2.14%, Ca 21.30%, O 51.02%. A byproduct of the wine industry. Prep'n from wine dregs: Dabul, U.S. pat. 3,114,770 (1963 to Orandi & Massera). See also the processes mentioned under L-tartaric acid.

Tetrahydrate, $\text{CaC}_4\text{H}_4\text{O}_6 \cdot 4\text{H}_2\text{O}$, powder. Slightly sol in water (from about 0.04% at 10° to about 0.2% at 85°) or in alcohol; sol in dil HCl or HNO_3 .

USE: As preservative for fruits, vegetables, seafoods; in deodorization of fish; as anticid.

Calcium Thiocyanate. Calcium rhodanate; calcium sulfocyanate. $\text{Ca}(\text{SCN})_2$; mol wt 156.24. $\text{Ca}_2\text{CaN}_2\text{S}_2$; C 15.37%, Ca 25.65%, N 17.93%, S 41.04%. Prep'n: *Gmelin's Handb. anorg. Chem.*, System no. 28 (Calcium), part B, 8th ed, pp 196, 972-976 (1958).

Tetrahydrate, $\text{Ca}(\text{SCN})_2 \cdot 4\text{H}_2\text{O}$, hygroscopic crystals or cryst powder. Dec on heating above 160°. Very sol in water; sol in methanol, ethanol, acetone. Keep well closed.

USE: In manuf of acrylonitrile polymers; for parchmentizing; for stiffening of textiles; soln as a solvent for textiles.



0013

Appendix i

YOUR PARTNER IN MATERIALS AND TECHNOLOGY

**CERAM
RESEARCH**

Queens Road Penkhull
 Stoke-on-Trent ST4 7LQ
 Tel: +44 (0) 1782 764444
 Fax: +44 (0) 1782 412331
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<http://www.ceram.co.uk>

TEST REPORT

BIOCOMPOSITES LTD
 ETRUSCAN STREET
 ETRURIA
 STOKE ON TRENT
 STAFFORDSHIRE
 ST1 5PQ
 FAO : J J COOPER

REPORT OF TESTS ON FORTOSS-CEMA

Your Reference BATCH NO: H34
 Ceram Sample(s) 990016674

Date Reported 15-Sep-99 Order/Job No 9909019
 Date Received 09-Sep-99 Date(s) of Test(s) 9/13-Sep-99

EXAMINATION BY X-RAY DIFFRACTION

Analysis of the sample using X-ray diffraction (XRD) gave the following results;

1. Identification and Quantitative Analysis.

The sample was found to consist of two crystalline compounds:

Phase	Mineral Name	Chemical Formula
Hemihydrate	Bassanite	$\text{CaSO}_4 \cdot 0.5\text{H}_2\text{O}$
Calcium Sulphate	Anhydrite	CaSO_4

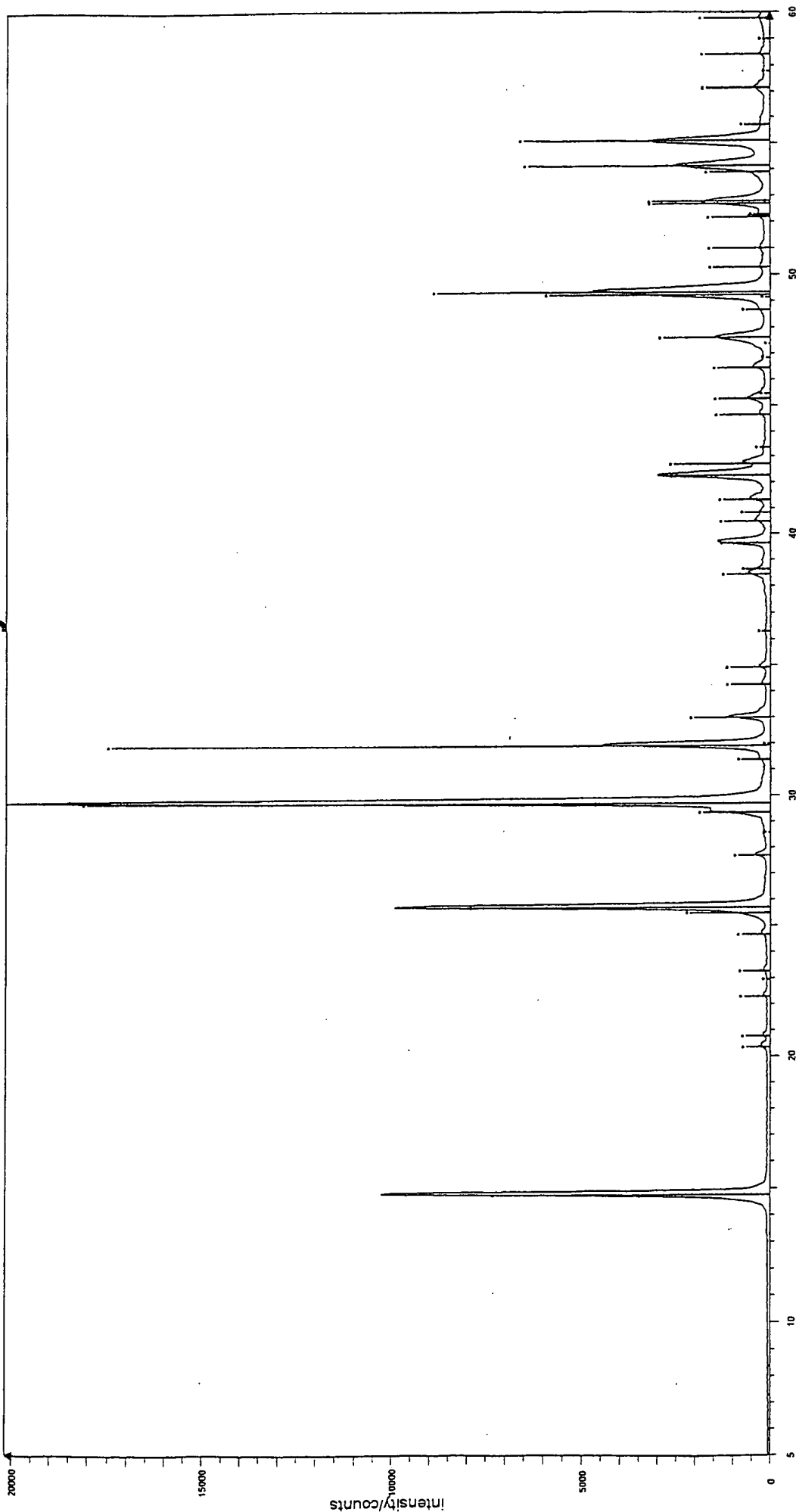
It was not possible to establish whether the anhydrite was the soluble or insoluble form due to peak overlap from Hemihydrate.

The amount of each phase was estimated quantitatively giving the following results;

Compound	Determined Wt%	Normalised Wt%
Hemihydrate	100	95.3
Anhydrite	4.9	4.7
Total	104.9	100

[Signature]
 Mrs TE Moran
 Authorised Signatory

CERAM Research X-ray Diffraction



File: 16674.raw - 16674/16564-Fortoss-Cerna Batch .H34 - Slit Meas.= Variable - Step: 0.020 ° - Step time: 3. s - Displ.: 0. mm
 Operations: Fourier 20,000 x 1 | Import
 41-0224 (l) - Bassanite, syn - CaSO4 0.5H2O - d x by: 1. - WL: 1.54056
 37-1496 (*) - Anhydrite, syn - CaSO4 - d x by: 1. - WL: 1.54056



0013

YOUR PARTNER IN MATERIALS AND TECHNOLOGY

**CERAM
RESEARCH**

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TEST REPORT

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 ETRUSCAN STREET
 ETRURIA
 STOKE ON TRENT
 STAFFORDSHIRE
 ST1 5PQ
 FAO : J J COOPER

REPORT OF TESTS ON CALCIUM SULPHATE

Your Reference CAPSET LOT 75950517 (EX 99/1309)
 Ceram Sample(s) 990016986

Date Reported 15-Sep-99 Order/Job No 9909019
 Date Received 15-Sep-99 Date(s) of Test(s) 15-Sep-99

Examination by X-ray Diffraction.

Analysis of the sample using X-ray Diffraction (XRD) gave the following results;

Identification and Quantitative Analysis.

The sample was found to consist of the following crystalline compounds;

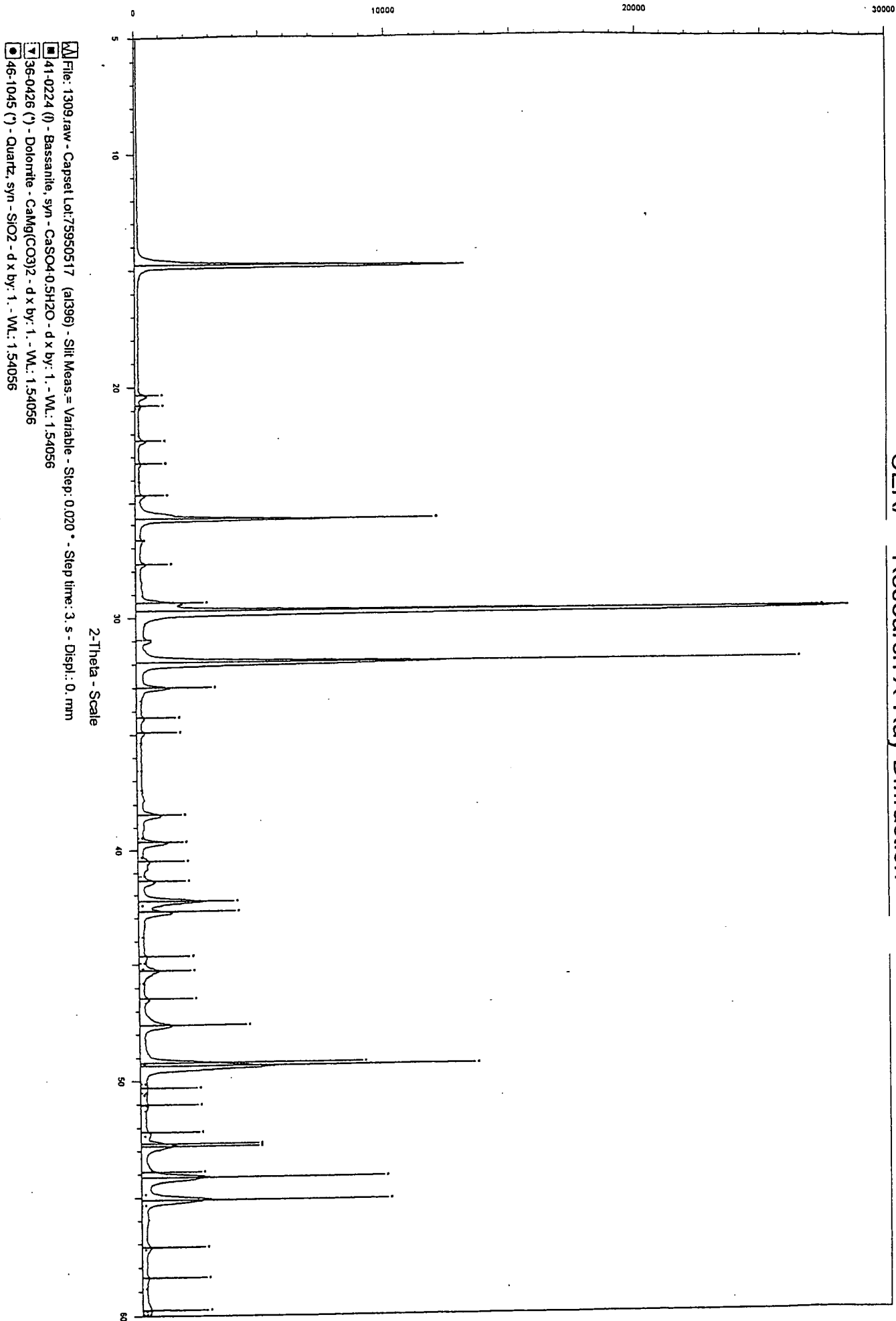
Phase	Chemical Formula
Bassanite	$\text{CaSO}_4 \cdot 0.5\text{H}_2\text{O}$
Dolomite	$\text{CaMg}(\text{CO}_3)_2$
Quartz	SiO_2
Unidentified	-

The amount of each phase was estimated quantitatively giving the following results;

Phase	Determined Wt %	Normalised Wt %
Bassanite	78	98.5
Dolomite	1.0	1.3
Quartz	0.2	0.3

Emy Moran
 Mrs TE Moran
 Authorised Signatory

CER/ Research X-Ray Diffraction



Press Release E012:99 - 11 February 1999

HSE publishes exposure assessment document on respirable crystalline silica

The Health and Safety Executive (HSE) has published the latest available figures on exposure to respirable crystalline silica.

HSE estimates that about 100,000 employees across a wide range of industries are routinely exposed to silica. The largest sectors affected are quarries, heavy clay, foundries, ceramics, construction and mining. Work activity with materials containing silica - such as sandstone and sand - can create dust - which can lead to a lung disease called silicosis, if inhaled over a period of time and possibly cancer.

Much of the data was collected as part of HSE's activities to review the existing Maximum Exposure Limit (MEL) for respirable crystalline silica at 0.3mg per cubic metre of air (as sampled by the International Standardization Organization for respirable dust).

The report aims to show how the setting of the MEL has influenced occupational exposure, and the data contained in the report may provide a useful baseline for future debate about carcinogenicity risk assessments. The report provides information on how industry has adopted controls to reduce exposure levels. It is however clear that certain industries, for example construction and stonemasonry, continue to have high levels of exposure.

Head of HSE's Chemical Agents Occupational Hygiene Unit, Barry Bord, said:

"Clearly some improvements have been made by British industry in reducing exposure to respirable crystalline silica but HSE is continuing to work with the various industries to reduce exposure to as low level as is practical."

Copies of Respirable Crystalline Silica - Exposure Assessment Document, ISBN 0-7176-1659-2, price £7.50, are available from HSE Books, PO Box 1999, Sudbury, Suffolk, CO10 6FS tel: 01787-881165 or fax: 01787-313995.

NOTES TO EDITORS

1. The International Agency for Research on Cancer (IARC) published a monograph in 1997 reviewing silica and placed it in Group 1 classification for carcinogenicity. IARC concluded that crystalline silica, inhaled in the form of quartz or cristobalite in occupational settings, is carcinogenic to humans.
2. The Health and Safety Commission's Advisory Committee on Toxic Substances Working Group on the Assessment of Toxic Chemicals (WATCH) were asked for a view on this classification, in anticipation of any debate within the European Union classification forum. In January 1998, WATCH concluded that the data best matched the data for a category 2 carcinogen. This means that there is sufficient evidence to presume that human exposure to respirable crystalline silica may result in the development of cancer.
3. The MEL of 0.4mg per cubic metre of air came into force on 1 January 1992. Employers can

not exceed this level but have a duty to reduce it as far as possible. On the 10th January 1997, the UK adopted the International Organization for Standardization convention for respirable dusts as defined in BS EN 401. To maintain an equivalent level of control the MEL for respirable crystalline silica was readjusted to 0.3 mg per cubic metre when sampled by the new convention.

PUBLIC ENQUIRIES:

Call HSE's InfoLine, tel: 0541-545500

or write to: HSE Information Centre, Broad Lane, Sheffield S3 7HQ.

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[Back to HSE Home Page](#)



MATERIAL SAFETY DATA SHEET

USG® Calcium Sulfate

MSDS NO. 05023

Page 1 of 3

United States Gypsum Company
125 South Franklin Street
Chicago, Illinois 60606-4678

Product Safety: 1 (800) 507-8899
Version Date: October 1, 1999
Version 3

SECTION I PRODUCT IDENTIFICATION

PRODUCT: USG® Calcium Sulfate

CHEMICAL FAMILY: Gypsum (Calcium Sulfate Dihydrate, $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$)

SECTION II INGREDIENTS

MATERIAL	%	TLV (mg/m ³)	PEL (mg/m ³)	CAS NUMBER
Gypsum	85-98	10	15(T)/5(R)	13397-24-5
Or Calcium Sulfate Dihydrate		10	15(T)/5(R)	10101-41-4
Limestone	0-10	10	15(T)/5(R)	1317-65-3
Crystalline Silica	<5	0.1(R)	0.1(R)	14808-60-7

(T) = Total (R) = Respirable

All ingredients of this product are included in the U.S. Environmental Protection Agency's Toxic Substances Control Act Chemical Substance Inventory. All components of this product are included in the Canadian Domestic Substances List (DSL) or the Canadian Non-Domestic Substances List (NDSL).

INFORMATION FOR HANDLING AND IDENTIFICATION OF CHEMICAL HAZARDS

NFPA Ratings: Health: 0 Fire: 0 Reactivity: 0 Other: N/A
HMIS Ratings: Health: 0 Fire: 0 Reactivity: 0
Personal Protection: Use eye and skin protection. Use NIOSH/MSHA-approved respiratory protection when necessary.
0 = Minimal Hazard 1 = Slight Hazard 2 = Moderate Hazard 3 = Serious Hazard 4 = Severe Hazard

SECTION III PHYSICAL DATA

Appearance and Odor: Off white to white powder; low odor
Melting Point: 1450°C - decomposes
Specific Gravity: 2.32 - 2.96
Solubility in Water: 0.26%

SECTION IV FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not combustible
Extinguishing Media: Use extinguishing media appropriate for surrounding fire.
Special Fire Fighting Procedures: None
Unusual Fire and Explosion Hazards: None



MATERIAL SAFETY DATA SHEET

USG® Calcium Sulfate

MSDS NO. 05023

Page 2 of 3

SECTION V HEALTH HAZARD DATA

This product can release nuisance dust in handling or during use. Eye, skin, nose, throat and upper respiratory irritation can occur with dust exposure.

EFFECTS OF OVEREXPOSURE:

ACUTE:

EYES: Direct contact can cause mechanical (particulate) irritation of eyes. If burning, redness, itching, pain or other symptoms persist or develop, consult physician.

SKIN: No toxic effects from powdered gypsum are noticed where air contains contaminate to excess. This material exhibits some affinity for moisture, and frequent exposures may have a drying effect on the skin. Possible itching and irritation may be experienced. This may lead to dermatitis.

INHALATION: Inhalation of dusts from this product may irritate the nose, throat, lungs, and upper respiratory tract. Persons subjected to large amounts of this dust will be forced to leave area because of nuisance conditions such as coughing, sneezing and nasal irritation. If respiratory symptoms persist, consult physician.

INGESTION: This product is gypsum. Gypsum is non-toxic, however, ingestion of a sufficient quantity could lead to mechanical obstruction of the gut, especially the pyloric region.

CHRONIC:

INHALATION: None known for gypsum. Prolonged and repeated exposure to respirable crystalline silica can result in lung disease (i.e., silicosis) and/or lung cancer.

EMERGENCY AND FIRST AID PROCEDURES:

EYES: Flush thoroughly with water for 15 minutes to remove particles. If irritation persists, consult physician.

SKIN: Wash with mild soap and water. A commercially available hand lotion may be used to treat dry skin areas. If skin has become cracked, take appropriate action to prevent infection and promote healing.

INHALATION: Leave the area of dust exposure and remain away until coughing and other symptoms subside. Other measures are usually not necessary, however, if conditions warrant, call physician.

INGESTION: Ingestion of sufficient quantity may result in mechanical obstruction of, the gut. If there is any discomfort, consult physician.

TARGET ORGANS: Eyes, skin, lungs, and respiratory system.

MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED: Pre-existing upper respiratory and lung disease such as, but not limited to, bronchitis, emphysema and asthma.

PRIMARY ROUTES OF ENTRY: Inhalation, eyes, and skin contact.

CARCINOGENICITY OF INGREDIENTS:

MATERIAL	IARC	NTP
Crystalline Silica	Group 1	Anticipated
In June, 1997, the International Agency for Research on Cancer (IARC) classified crystalline silica (quartz and cristobalite) as a human carcinogen. In making the overall evaluation, the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied. Carcinogenicity may be dependent on inherent characteristics of the crystalline silica or on external factors affecting its biological activity or distribution of its polymorphs.		
IARC states that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1).		

SECTION VI REACTIVITY DATA

STABILITY:	Stable
INCOMPATIBILITY:	Acids
HAZARDOUS POLYMERIZATION:	Will not occur.
HAZARDOUS DECOMPOSITION:	Above 1450°C could produce SO ₂ & CaO.



MATERIAL SAFETY DATA SHEET

USG® Calcium Sulfate

MSDS NO. 05023

Page 3 of 3

SECTION VII SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Avoid creating excessive dust. Wear appropriate protective equipment. Scoop up material from spillage into a waste container for disposal, or if not contaminated by foreign material it may be reclaimed for processing.

WASTE DISPOSAL METHOD:

Dispose of in accordance with local, state and federal regulations.

SECTION VIII SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION:

Not typically necessary under normal conditions of use. Avoid inhalation of dust. Dust created from mixing or handling may cause eye, nose, throat or upper respiratory irritation. Wear a NIOSH/MSHA-approved dust respirator if TLV is exceeded and/or when dusty conditions exist. Provide general ventilation and/or local exhaust ventilation to meet TLV requirements.

PROTECTIVE EQUIPMENT:

Gloves or protective clothing are usually not necessary but may be desirable in specific work situations. Wear adequate clothing to minimize drying of skin. Wear safety glasses or goggles for eye protection to avoid particulate irritation of the eye.

SECTION IX SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:

Store in a dry place. Minimize exposures in accordance with good industrial hygiene practice. During handling wear the appropriate respiratory, eye and skin protection if warranted per environmental conditions.

ΔCAUTION!

Dust may cause eye, skin, nose, throat or upper respiratory irritation. Avoid inhalation of dust and eye contact. Provide good general ventilation and/or local exhaust to reduce dust exposure. If dusty conditions exist, use NIOSH/MSHA-approved respiratory protection. Wear eye protection to avoid particulate irritation of eye. If eye contact occurs, flush thoroughly with water for 15 minutes. If irritation persists, call physician. Product safety information (800) 507-8899.

KEEP OUT OF REACH OF CHILDREN

END